innovative needle safety devices

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more products. better treatments. reliably supplied.
Injectable Drug Device Market-Growth and Trends

Driving Trends:
- Increasing self-administration
- Patient and caregiver convenience
- Targeted drug delivery
- The need for safety mechanisms for injectables
- An increase in the prevalence of chronic diseases such as RA etc.
- The need for differentiation and protection from generic competition
The need for safety mechanisms for injectables:

Needle stick injuries affect millions of health care workers around the world every year, exposing them to potentially life-threatening illness.

Both the US, since 2000 and Europe beginning in 2013 have mandated the use of needle safety devices.

To meet this vital need, Catalent Pharma Solutions has formed a collaboration with Innovate to offer the Protector Safety Shield System™
Innovative injectable safety technologies to satisfy growing market demand

In collaboration with Innovate, Catalent now offers:

- The Protector Safety Shield System™
  - Can be fitted to any syringe size and format
  - Effective yet simple 3 part manufacturing process
  - No alteration of filling lines necessary

- The Click In Safety System
  - Available as fully-integrated pre-filled or stand alone
  - Staked needle, Luer Lock or Luer Slip Syringe

- Easy-to-use
- Cost effective choices for our customers
- Offering clinicians and patients maximum protection
Catalent’s Pre-Filled Syringe offerings are extensively customizable and support numerous therapeutic areas.

Capacity greater than 200 million

- Extensive range of pre-filled syringe sizes (0.5mL to 50mL)
- Syringe top: luer, luer lock or with needle
- Graduation of syringes
- Filling of viscoelastics
- 100% visual control: fully-automatic, semi-automatic or manual
- Aseptic/terminal sterilization of filled syringes
- Labeling, blistering and cartoning of syringes
Catalent is an Industry Leader in Aseptic Processing

Over 25 years of providing specialized scientific and manufacturing expertise in complex fill finish treatments

An extensively customizable range of containers, tailored to meet the unique needs of each customer, across markets such as biologics; peptides; Ophthalmic, Respiratory & Topical

Scalable capacity to meet customer demand through its network of manufacturing sites

Operates with the highest quality standards in the industry
A unique solution
Partnering with Catalent Pharma Solutions
Flexibility with the ability to deliver
Fast track options for customized solutions
“Off the shelf” product range
Large scale manufacturing
Simple ideas converted to inexpensive product
 Formats

Integrated - Very expensive and bulky no clinical choice

Click in - Very expensive and bulky

Retractable - Expensive and not always reliable

Sliding sheath - Difficult to lock and can be cumbersome

Flick up /push down – Cross infection risk, disliked

Directly sheathed needle - Flimsy and can hurt the patient
Surface Activated

Initially seen as cheapest systems

Can be added after filling

Disliked by clinicians – flimsy, obstructive

New study shows splash

Major cross infection risk

Likely to have major restrictions on future use
Splash Study Conclusions:

Cross infection was left on the surfaces from Splatter/splash and drip onto device!

- Both studies found splatter was possible
- In fact when fluid was left in the syringe splatter was likely
- In effect the needle stick injury problem had been replaced with contamination and cross infection
- Further studies planned to look at mouth or eye splash
Protector Safety Shield™

A simple replacement for standard needles
Easy to use little change to normal clinical practice
For use with plastic or glass luer-lock syringes
Clear view does not obstruct needle
No risk of splash contamination
Very cost effective
Segregation of waste
Protector Safety Shield™: Simple and Safe Use

1. Attach
2. Inject
3. Lock
4. Separate
Click In Safety Shield System

Simple active device
Very cost effective
Can be added by physician
Can be added at end of filling line
Wide range of syringe sizes
Not surface activated so no splash
Complies with USA and European safety legislation
Found to be very simple to use and lock out in nurse led trial
Click In Safety Shield System

1. Click in

2. Administer Injection

3. Slide Sheath over needle

4. Lock in place
Nurse led trial 2010 UK

Overall satisfaction with the device

- Good and Excellent: 20
- Fair and Poor: 0

Response

- Frequency

March 2011
Conclusions

Legislative changes make it necessary to provide needle safety:

• You are not asked to provide an expensive solution
  – only a safe one

• It is key to ensure you are not replacing one problem with another (surface activated cross infection)

• The Protector safety shields can provide all your needle safe solutions cost effectively without the need to alter your fill line.
Catalent and Innovate UK: Innovative solutions for the drug device market

Combined offering

Proprietary active safety shield device technology

Syringe filling, safety device assembly and packaging

Supply of final product

One-stop solution for customers